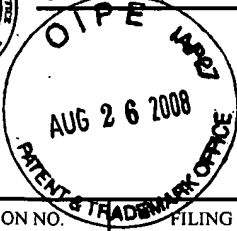




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|--|-------------|----------------------|-------------------------|------------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/537,891 | 06/17/2005 | Johnathan A Napier | 13478-00001-US | 7537 |
| 23416 7590 08/20/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899 | | | EXAMINER ZHENG, LI | |
| | | | ART UNIT 1638 | PAPER NUMBER |
| | | | MAIL DATE 08/20/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/539,891 | Applicant(s) NAPIER ET AL. | |
| | Examiner LI ZHENG | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: <u>20080812</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 23, 2008 has been entered.

As a result, claims 1-5 and 7-9 and 26 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

Claim Rejections - 35 USC § 112

4. Claims 1, 3-5, 7-9 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed April 11, 2008. Applicants traverse in the paper filed May 23, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the present application directs to a process rather than the nucleotide sequence that are used for practicing the claimed process and that a particular nucleic acid is not essential to the claimed method (response, the paragraph bridging pages 5-6).

The office contends that the nucleotide sequences used in the process still need to meet the written description requirement. As discussed in previous actions, only very limited number of genes encoding delta-5- and delta-8-desaturases are disclosed in the prior art and they are not considered be representative of the genus. Further, delta-9-elongase is not well known in the art at the time of the instant invention. Therefore, it is concluded that Applicants are not in possession of a method of using any delta-5-, delta-8-desaturases and delta-9-elongases.

Applicants further argue that possession of an invention can be shown in variety of ways including description of an actual reduction to practice (response, page 6, 3rd paragraph).

The Office contends that the reduction to practice may provide support for specific delta-9-elongase, delta-5- and delta-8-desaturase, the reduction to practice fails to show possession for the invention in full scope.

Applicants further argue that since other delta-9-elongase, delta-5- and delta-8-desaturase would be expected to perform the same enzymatic conversions in the context of the claimed process, disclosure of more species is not necessary to show possession of the entire genus (response, page 6, 4th paragraph).

The Office contends that the instant invention requires not the enzyme but the nucleotide sequences encoding the enzymes. Therefore, simply knowing the other members would perform the same enzymatic conversions is not enough to show possession of the genus which encompass any nucleotide sequences encoding any delta-9-elongase, delta-5- and delta-8-desaturase from any organism.

5. Claims 1-5, 7-9 and 26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for accumulate C20 polyunsaturated fatty acids in transgenic plant expressing nucleotide sequences encoding SEQ ID NO: 2,4 and 6, does not reasonably provide enablement for any transgenic plant expressing any delta-9-elongase, any delta-5- and delta-8-desaturase to produce any compound shown in formula I of claim 1 with a content of at least 1% by weight. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for the reasons of record stated in the Office

action mailed April 11, 2008. Applicants traverse in the paper filed May 23, 2008.

Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the claimed subject matter relates to a process and the individual genes encoding delta-9-elongase, elta-5- and delta-8-desaturase are not being claimed (response, page 7, 5th paragraph). Applicants further argue that it is merely routine experimentation to identify other delta-9-elongase by using instantly-disclosed sequence as a probe (response, the paragraph bridging pages 7-8).

The Office contends that the genes used in the claimed process are not well known especially for delta-9-elongase. Further, to identify and isolate those un-exemplified genes is undue without further guidance. Therefore, in contrast to Applicants' conclusion that to screening and testing delta-9-elongase, any delta-5- and delta-8-desaturase activity in plant is routine and is not undue experimentation, the Office maintains that undue experimentation is required for a person skilled in the art to clone un-exemplified genes encoding delta-9-elongase, any delta-5- and delta-8-desaturase by using PCR or hybridization, to verify its activity, to make the plant expression cassettes expressing all three genes, to transform plants therewith, and to confirm that the transgenic plants have the claimed content for all the compounds described in claim 1. Still further, it is not known whether the nucleotide sequences encoding delta-9-elongases from various plants. Therefore the instant -disclosed sequence may be used as probe to identify other closely related genes from closely related plant species of Arabidopsis, without further guidance undue experimentation

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would have been required to use instant -disclosed sequence as probes to identify other gene encompassed by the claims from not closely related plants.

Still further, the working example in the specification only shows the data for the content of C16, C18 and C20 polyunsaturated fatty acids such as the ones listed in table 1, it does not provide any evidence that other compounds in the formula I of claim 1 are produced by the instant method. There is no evidence that the transgenically expressed enzymes would produce such unmanageable number of compounds as depicted in claim 1.

Summary

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/
Examiner, Art Unit 1638

| | | | |
|--------------------------|--------------------------------------|--------------------------------------|--|
| Interview Summary | Application No. 10/539,891 | Applicant(s) NAPIER ET AL. | |
| | Examiner LI ZHENG | Art Unit 1638 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) LI ZHENG.

(3) Hui-ju Wu.

(2) Elizabeth McElwain.

(4) Roberte Makowski.

Date of Interview: 7/23/08.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: 1-5,7-9 and 26.

Identification of prior art discussed: none.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: rejections under U.S.C 112, First Paragraph, were discussed. Although no agreement was reached, both sides felt that the interview was helpful for expediting the prosecution.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Li Zheng/

Examiner, Art Unit 1638

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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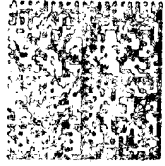
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